7 August 2000 1724 Alpine Drive Carrollton, TX 75007-3740

FOOD & DRUG ADMINISTRATION

Dockets Management Branch [HFA-305]
Food & Drug Administration
Michael Friedman, MD
Lead Deputy Commissioner
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0001

1900 °00 AUG 10 A10:39

Dear Doctor Friedman:

Subject: Labeling Supplements

- 1. When one orders Dietary Supplements from sellers' advertisements there are unnecessary risks involved.

 Those risks could be eliminated if the FDA would *make it <u>mandatory</u>* for sellers to *list all ingredients* and mineral *elemental* amounts in their advertisements.
- 2. For example I purchased the following Dietary Supplements advertised as:
 - ◆ Manganese 50 mg. without stating elemental amounts.
 - ◆MSM [Methylsulfonylmethane] 200 mg.
 - ♦Zinc Gluconate 50 mg.
 - ◆Selenomethionine 200 mcg.

After arriving "Other Ingredients" labels showed unstated amounts of Dicalcium Phosphate.

Other sellers provide products without Dicalcium Phosphate but one does not know until after money is spent and, perhaps wasted. Licensed medical practitioners tell us that:

- ♦ Dicalcium Phosphate is another name for Phosphoric Acid which causes Calcium losses from Bones and Teeth.
- ◆ Calcium loss can lead to Osteoporosis and other health problems.

Thus the public is being misled by advertisements for supposedly healthful products which may actually be harmful to their health. One pays "Shipping and Handling" charges and returning the bottles adds unnecessary expenses for return postage and getting nothing of value.

- 3. Another set of examples are:
 - Glucosamine Sulfate and Chondroitin Sulfate Plus does not show the Sulfate amounts and "Other Ingredients" labels also show:
 - *Ascorbic Acid [Vitamin C]!
 - •Some, as I am, are unfortunately allergic to vitamin C.
 - •Calcium [270 mg.] which is a fair amount.
 - Those also taking Calcium supplements may not need to take as much in Calcium supplements.
 - •Manganese Glycinate [20 mg.] represents some unknown % of *elemental Manganese* which is important. If one also took Manganese supplements the totals might pose health problems for some.
 - ♦ Chlorophyll 50 mg. gel caps may also contain unknown amounts of "Chlorophyllin Copper Complex".

How much Copper can one safely take and what is the "Complex"?

- *Since 1995, to prevent daily migraines, I must take 15 *Chlorophyll* gel are required three [3] times a day about 30 minutes before each meal.
- •Sometimes an additional 15 gel caps are needed when some unknown substance is taken which has *vitamins B and/or C* to which I am *very allergic* and cause migraines.
- 4. Also Dietary Supplements may contain other ingredients to which individuals may be allergic yet not aware of the problems unless labels are read. For example unfortunately I am very allergic to vitamin C also known as Ascorbic Acid.

Having bought and taken Dietary Supplements without knowing they also contained Ascorbic Acid results in migraines without knowing the reason. Product examples appear to be numerous.

5. Starting at age 9 I had daily severe migraine headaches without knowing the reason.

One doctor removed my appendix falsely thinking it would stop the headaches.

In 1964 a doctor prescribed three [3] Sansert tablets daily which stopped migraine headaches.

Unfortunately as time progressed more and more Sansert tablets were required to stop/prevent migraines. For several years I had

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to take 18 tablets at one time and sometimes another 18 about two [2] hours later.

In 1975 I read in a 1907 issue of the New England Journal of Medicine that foods caused 78% of migraines!

Eliminating various foods from my diet showed *rice* and *potatoes* to be my <u>only</u> *non-allergic foods*. A steady diet of only rice and potatoes isn't very practical so Sansert was continued.

In 1994 a surgeon thought my left lung contained "Pneumonia Scar Tissue" and operated to scrape the insides of the lung. On the outside of my left lung, he found a *Tumor* which he described as looking like "Crazy Glue" and initially diagnosed it as with the tumor resulting but I had no other choice.

In 1995 a licensed medical practitioner suggested Wheat Grass and Chlorophyll which did eliminate the food toxins and stopped my migraines.

I require fifteen [15] 50 mg. Chlorophyll gel caps three [3] times daily before meals to prevent migraines. Sometimes when unsuspectedly taking ingredients with vitamins B or C my migraines return and taking another 15 gel caps eliminates those migraines. So you see Chlorophyll is necessary for me.

- 6. The general public may/may not read the "Other Ingredients" labels and be deceived into taking harmful ingredients.
- 7. Requiring mandatory correct labeling of all ingredients will likely result in some sellers being eliminated and higher prices but the public could be better protected.

Cordially,

M. C. Mead

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